

Amendments to the Claim:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-58 (cancelled).

59 (Currently Amended). A kit for inducing an immune response in a human toward an infectious disease to which a human subject and thereby use to protect said subject a mammal against an infectious disease to which a mammal human is susceptible, said kit comprising one or more containers, each container holding one or more pharmaceutically acceptable doses of one or more immunogens, at least one of said immunogens acting to protect against said infectious disease when appropriately administered to said subject in suitable amounts at suitable times,

said kit comprising at least a single dose of at least two different immunogens, each capable of inducing an immune response against the same infectious disease, said kit providing at least two such immunogens in different amounts,

wherein at least one of the following conditions holds:

- (1) said kit comprises at least two different capsular pneumococcus immunogens, each conjugated to at least one carrier protein,
- (2) said kit comprises at least two different capsular meningococcus immunogens, each conjugated to at least one carrier protein,
- (3) said kit comprises at least two different acellular pertussis immunogens, or
- (4) said kit comprises at least two different purified viral capsid immunogens,

wherein the kit is manufactured by a process comprising accepting at least one lot of at least one immunogen for use in production of the kit after determining a dose of at least one said immunogen is safe according to a method of

a) comparing the incidence, prevalence, frequency or severity of a chronic immune-mediated disorder, or the level of a marker of such a disorder, in a treatment group of humans immunized according to an immunization schedule with one or more doses of said immunogen, with that in a control group of humans
and/or

b) comparing the risk of a chronic immune-mediated disorder in a first group of humans immunized according to an immunization schedule with one or more doses of said immunogen, with that in a second group of humans, said first group of humans having been immunized with one or more doses of said immunogen according to a first screened immunization schedule, and the second group of humans having been immunized with one or more doses of said immunogen according to a second screened immunization schedule, each group of humans having been immunized according to a different immunization schedule,

said immunization of (a) or (b) inducing an immune response, comprising production of antibodies or activation of T-cells, in at least one such group

said kit comprising labeling containing information
(a) that the kit can be used to reduce the incidence or severity of a chronic immune-mediated disorder in a mammal,

and providing instructions for the prophylactic or therapeutic use of said immunogens to reduce the incidence or severity of a chronic immune-mediated disorder in a mammal, said instructions stating that one or more doses should be administered according to an immunization schedule set forth in said instructions, said immunogens, when so administered, acting to substantially reduce the incidence or severity of said chronic immune-mediated disorder,

or

(b) that at least one immunogen of the kit, when administered according to one or more immunization schedules, may, can or does, or has been reported to, increase the incidence or accelerate the onset of a chronic immune-mediated disorder,

or

(c) regarding any animal study or clinical study of the effect of any of said immunogens, or of any immunization schedule for any of said immunogens, on the incidence of a chronic immune-mediated disorder, or on the time of onset of said disorder.

60 (previously presented). The kit of claim 59 where

(a) applies.

61 (previously presented). The kit of claim 59 where
(b) applies.

62-83 (Cancelled).

84 (Currently amended). The kit of any one of claims 59, 60, 61, 62, 108, 116, 277, 278, 279, 294, 298, 300, 301, 305, 306, 307, 308, 309, 310, 311, 96, 97, 30, 49, 55, 74, 77, 90-92, 98-100, 106, 115-117, 125 or 126 in which the disorder is non-streptozotocin-induced diabetes and where said mammal is human.

85-107 (Cancelled).

108 (currently amended). The kit of claim 59, said kit further comprising a label for each container indicating the

identity and amount of each of said immunogens in such container.

109-115 (Cancelled).

116 (currently amended). The kit of claim ~~16~~ 59 which comprises at least a first immunogen capable of inducing an immune response against a first infectious disease and at least a second and different immunogen capable of inducing an immune response against a second and different infectious disease, and thereby protects, when said immunogens are administered in suitable amounts at suitable times, is for use to protect against at least two different infectious diseases, and provides at least one immunogen protecting against each of said diseases.

117-276 (Cancelled).

277 (Currently Amended). The agent kit of claim 59 ~~267~~ where (2) applies at least one of said non-pediatric carbohydrate immunogens is a meningococcus immunogen.

278 (Currently Amended). The agent kit of claim 59 ~~267~~ where (1) applies at least one of said non-pediatric carbohydrate immunogens is a pneumococcus immunogen.

279 (Currently Amended). The agent kit of claim 59 ~~267~~ where said immunogenic agent comprises a first non-pediatric carbohydrate immunogen conjugated to a first carrier protein and a second non-pediatric carbohydrate immunogen conjugated to a second and different carrier protein.

280 (Cancelled).

281 (Currently Amended). The agent kit of claim 59 ~~267~~ where said associations are statistically significant.

282-291 (Cancelled).

292 (Currently Amended). The agent kit of claim 84 ~~267~~ wherein the risk of a chronic immune mediated disorder is determined at least one year after immunization.

293 (Cancelled).

294 (Currently Amended). The agent kit of claim 59 ~~290~~ where said immunogenic agent comprises at least two

different carrier proteins.

295-297 (Cancelled).

298 (Currently Amended). ~~A pharmaceutically acceptable immunogenic agent The kit of claim 59 which comprises at least one non-pediatric immunogen, where at least one such non-pediatric immunogen is a carbohydrate immunogen, other than a hemophilus immunogen, conjugated to a carrier protein, where said agent, administered to a human child according to an immunization schedule starting at less than 16 weeks after birth results in protection against at least one infectious disease.~~

299 (Currently Amended). ~~A pharmaceutically acceptable immunogenic agent The kit of claim 59 which comprises immunogens when administered to a human child according to an immunization schedule starting at less than 16 weeks after birth resulting in adequate protection against at least diphtheria, tetanus, pertussis, where more than one a acellular pertussis immunogens are included, where said agent also comprises at least one more immunogen, where said at least one immunogen is a pediatric immunogen, and where the administration of said at least one immunogen is associated with an acceptable risk of development of one or more chronic immune mediated disorders.~~

300 (Currently Amended). The ~~agent~~ kit according to claim 59 ~~299~~ and which is substantially free of immunomodulators, other than immunogens, which are not aluminum or calcium salts or other depot adjuvants.

301 (Currently Amended). The ~~agent~~ kit according to claim 300 which is substantially free of aluminum salts.

302-303 (Cancelled).

304 (New). The kit of any one of claims 267, 287, 289, 290, 291, 292 or 293, wherein at least one immunogen is a capsular polysaccharide conjugated to a non-toxic form of diphtheria or tetanus toxin.

305 (New). The kit of claim 304, wherein at least one

immunogen is a capsular polysaccharide conjugated to a non-toxic form of diphtheria toxin.

306 (New). The kit of claim 59, said kit comprising one or more containers, each container holding one or more pharmaceutically acceptable doses of one or more immunogens, at least one of said immunogens acting to protect against said infectious disease when appropriately administered to said subject,

said kit comprising labeling containing information

(a) that the kit can be used to reduce the incidence or severity of a chronic immune-mediated disorder in a mammal, and providing instructions for the prophylactic or therapeutic use of said immunogens to reduce the incidence or severity of a chronic immune-mediated disorder in a mammal, said instructions stating that one or more doses should be administered according to an immunization schedule set forth in said instructions, said immunogens, when so administered, acting to substantially reduce the incidence or severity of said chronic immune-mediated disorder,

or

(b) that at least one immunogen of the kit, when administered according to one or more immunization schedules, may, can or does, or has been reported to, increase the incidence or accelerate the onset of a chronic immune-mediated disorder,

or

(c) regarding any clinical study of the effect of any of said immunogens, or of any immunization schedule for any of said immunogens, on the incidence of a chronic immune-mediated disorder, or on the time of onset of said disorder.

307 (New). The kit of claim 306 where (a) applies.

308 (New). The kit of claim 306 where (b) applies.

309 (New). The kit of claim 308, said labeling further comprising instructions for administering such immunogens so

as to avoid such increase in the incidence or severity, or such acceleration in the onset, of said chronic immune-mediated disorder.

310 (New). The kit of claim 59 wherein (3) applies.

311 (New). The kit of claim 59 wherein (4) applies.

312 (New). The kit of claim 59 wherein at least one immunogen is genetically engineered.

313 (New). The kit of claim 59 wherein at least one container comprises at least 3 different immunogens.

314 (New). The kit of claim 59 wherein at least one container comprises at least 4 different immunogens.

315 (New). The kit of claim 59 wherein at least one container comprises at least 5 different immunogens.

316 (New). The kit of claim 59 wherein at least one container is a single dose container.

317 (New). A pharmaceutically acceptable kit for use to protect a mammal against an infectious disease to which a mammal is susceptible, said kit comprising one or more containers, each container holding one or more pharmaceutically acceptable doses of one or more immunogens, at least one of said immunogens acting to protect against said infectious disease when appropriately administered to said subject,

wherein at least one of said immunogens is an immunogen other than a BCG, diphtheria, pertussis, polio, hepatitis A, hepatitis B, hemophilus influenza, measles, mumps, or rubella immunogen,

wherein the kit is manufactured by a process comprising, for at least one immunogen, accepting at least one lot for use in production of the kit after said immunogen is determined to be safe according to a method of

a) comparing the incidence, prevalence, frequency or

severity of a chronic immune-mediated disorder, or the level of a marker of such a disorder, in a treatment group of humans immunized according to an immunization schedule with one or more doses of said immunogen, with that in a control group of humans, and/or

b) comparing the risk of a chronic immune-mediated disorder in a first group of humans immunized according to an immunization schedule with one or more doses of said immunogen, with that in a second group of humans, said first group of humans having been immunized with one or more doses of said immunogen according to a first screened immunization schedule, and the second group of humans having been immunized with one or more doses of said immunogen according to a second screened immunization schedule, each group of humans having been immunized according to a different immunization schedule,

said immunization of (a) or (b) inducing an immune response, comprising production of antibodies or activation of T-cells, in at least one such group.

318 (New). A method of making a pharmaceutically acceptable kit for use, prophylactically or therapeutically, in the immunization of a mammalian subject against at least one infectious disease

(a) providing at least one immunogen which is protective, after one or more doses, against at least one infectious disease,

(b)

(1) comparing the incidence, prevalence, frequency or severity of a chronic immune-mediated disorder, or the level of a marker of such a disorder, in a treatment group of humans immunized according to an immunization

schedule with one or more doses of said immunogen, with that in a control group of humans, and/or

(2) comparing the risk of a chronic immune-mediated disorder in a first group of humans immunized according to an immunization schedule with one or more doses of said immunogen, with that in a second group of humans, said first group of humans having been immunized with one or more doses of said immunogen according to a first screened immunization schedule, and the second group of humans having been immunized with one or more doses of said immunogen according to a second screened immunization schedule, each group of humans having been immunized according to a different immunization schedule,

said immunization of (1) or (2) inducing an immune response, comprising production of antibodies or activation of T-cells, in at least one such group,

(c) providing at least one container, and introducing one or more doses of one or more tested immunogens into said container, and

(d) assembling the container or containers comprising said immunogens into a kit.

319 (New). The method of claim 318, further comprising labeling said container or containers, or said kit.

320 (New). The method of claim 319, said labeling providing instructions for the use of said kit to immunize a mammalian subject against at least one infectious disease.

321 (New). The method of claim 320, said testing including testing of said immunogen when used according to said instructions.

322 (New). A method of making a pharmaceutically acceptable immunogenic agent comprising pharmaceutically

acceptable amounts of each of one or more immunogens, said immunogens being protective, after one or more doses, against at least one infectious disease,

(a) providing at least one immunogen which is protective, after one or more doses, against at least one infectious disease,

(b)

(1) comparing the incidence, prevalence, frequency or severity of a chronic immune-mediated disorder, or the level of a marker of such a disorder, in a treatment group of humans immunized according to an immunization schedule with one or more doses of said immunogen, with that in a control group of humans, and/or

(2) comparing the risk of a chronic immune-mediated disorder in a first group of humans immunized according to an immunization schedule with one or more doses of said immunogen, with that in a second group of humans, said first group of humans having been immunized with one or more doses of said immunogen according to a first screened immunization schedule, and the second group of humans having been immunized with one or more doses of said immunogen according to a second screened immunization schedule, each group of humans having been immunized according to a different immunization schedule,

said immunization of (1) or (2) inducing an immune response, comprising production of antibodies or activation of T-cells, in at least one such group,

and

(c) packaging at least one dose of said immunogen into

said immunogenic agent.

323 (New). The kit of claim 304 in which the disorder is non-streptozotocin-induced.

324 (New). The kit of claim 59 wherein the risk of a chronic immune mediated disorder is determined at least one year after immunization.